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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

BARBOURVILLE NURSING HOME Petitioner-Appellant, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and MICHAEL O. LEAVITT, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Respondent-Appellee.	)	On Appeal from the Departmental Appeals Board of the United States Department of Health and Human Services

Before: **BOGGS, Chief Judge; BATCHELDER, Circuit Judge; and WEBER, District Judge**[*]

PER CURIAM. The federal government, through the agency of the Department of Health and Human Services ("Department"), requires facilities that choose to participate in the Medicare or Medicaid programs to comply with certain minimum standards of care. Based on the unsanitary actions of its staff while treating nursing home patients during a June 2001 compliance survey, the Department found Barbourville Nursing Home ("BNH" or "Facility"), a Medicare participant, to

[*]The Honorable Herman J. Weber, United States District Judge for the Southern District of Ohio, sitting by designation.

have been substantially noncompliant with the standards of care in the Medicare regulations. BNH does not challenge that finding, nor does the Facility specifically challenge the Department's imposition of civil money penalties ("CMP") for noncompliance. Instead, BNH challenges the determination that its noncompliance created an "immediate jeopardy" to its residents' safety, a severity that warranted the highest level of penalties. An administrative law judge ("ALJ") upheld the "immediate jeopardy" findings, and the Departmental Appeals Board ("DAB" or "Board") later affirmed. BNH now appeals to this court, arguing that the Department's immediate jeopardy findings were not supported by substantial evidence. We affirm.

I

Based in Barbourville, Kentucky, BNH is a skilled nursing facility participating in the federal Medicare and Medicaid programs. To continue participating in the federal programs, such facilities must comply with certain health and safety requirements, and the Centers for Medicare and Medicaid Services ("CMS"), the Department's enforcement agency, assesses compliance through surveys that are typically conducted by state agencies.[1] In June 2001, the Commonwealth of Kentucky's Office of Inspector General ("OIG"), pursuant to an agency agreement with CMS, conducted a survey of operations at BNH. During this time, OIG's surveyors uncovered and

[1]Survey findings list deficiencies (expressed as so-called "F-Tags" or "Tags"), the regulations to which they relate, the surveyors' determinations as to scope and severity of deficiencies, and specific findings that would support each deficiency determination. The scope and severity of each deficiency is determined in accordance with the factors set forth in 42 C.F.R. § 488.404(b): the severity determination ranges from "no actual harm with a potential for minimal harm" to "immediate jeopardy to resident health or safety."

observed numerous instances where BNH did not act in substantial compliance with the minimum standards of care required by law. Specifically, the surveyors determined that BNH was noncompliant with respect to 29 separate items, and OIG further found that at least three of those violations were so serious that they warranted the immediate jeopardy level of severity. We shall limit our discussion to the acts that were found to have risked immediate jeopardy to the residents. We shall refer to specific residents by code number, as did the surveyors, to ensure patient confidentiality.

During the observation of Resident 4's pressure sore treatment, the nurse began by using a pair of unsanitized scissors that she had removed from her pocket to change pressure sore dressings. While she was changing the soiled dressing on the resident's coccyx, the resident had a bowel movement "and feces were observed on the resident's peri-anal area, under [the] pad, and bed sheets." The nurse wiped the resident's coccyx sore with a pad and, though the resident continued to move her bowels, the nurse simply placed new dressing on the sore, thereby "covering the pressure sore and the fecal material on the resident's skin directly below the pressure sore." That nurse and another staff member then proceeded to clean the fecal material from the resident's skin, pushing it "up under the dressing on the resident's coccyx." During this process, the nurse was observed cleaning the fecal material from the resident's peri-anal area by wiping "the stool from the back (anal area) to the front (supra-pubic area)" despite the fact the resident had a Foley catheter in place in her urethra. When finished, the nurse repositioned the resident "in bed while wearing the same soiled gloves that the nurse had worn when she cleansed the stool from the resident's skin."

A different nurse was observed changing Resident 2's pressure sore dressings. This nurse also began by cutting soiled dressing with a pair of unsanitized scissors that had been in her pants pocket. She used the same contaminated scissors to cut clean dressing that was then applied to the resident's sores, and continued to reuse those same scissors. The nurse placed the soiled dressing materials in a bag that later contaminated her box of personal cleansing washcloths, yet the nurse and the staff assistant continued to use cloths from that contaminated box to cleanse their hands.

Surveyors also found fault with Resident 2's general pressure sore care. The resident had been admitted on November 17, 2000 with a history of vulnerability to pressure sores, but there is no evidence that any assessment of the resident's skin had been conducted at the time of admission, despite the Facility's own written policies. Nevertheless, an examination on November 30 indicated that the resident had developed an advanced pressure sore that was "purple, black and necrotic" on her left heel. Yet the Facility's medical records indicated that the staff had applied heel protectors daily, which should have provided the staff with a daily opportunity to observe the resident's skin in that area. Therefore, surveyors found that the resident developed a avoidable pressure sore at the Facility in spite of BNH's record of care, and BNH does not refute that finding.

The same nurse who treated Resident 2 made similar and more egregious mistakes with Resident 13. The resident had a bowel movement while the nurse changed her pressure sore bandages "and feces were observed on the resident's peri-anal area as well as on the resident's bed sheets." But the nurse simply "push[ed] the fecal matter away from the Stage II pressure sore on the resident's coccyx with the bed sheet without thoroughly cleansing the resident of stool prior to

performing the dressing change." The nurse then contaminated a tube of ointment by touching the tip of the tube to the resident's sores, but she continued to use the same tube on the resident's other sores. When some of the contaminated ointment slid off the resident's sore and onto the surrounding skin that was contaminated by feces, the nurse "was observed to take the Vigilon dressing and scoop the ointment from the resident's skin onto the Stage II pressure sore." She then used the same gloves that she had previously employed to dress the pressure sore on the resident's contaminated coccyx to reposition the resident's body after the treatment was complete.

As a result of these findings, the surveyors concluded that the Facility had failed to conform to the applicable regulations. Specifically, the surveyors found that their "[r]eview of the facility's infection control program revealed that the facility failed to have an effective infection control program to ensure that the facility staff were providing pressure sore treatments utilizing accepted infection control techniques to prevent the spread of infection." Therefore "[t]his failure to provide pressure sore treatment in accordance with accepted infection control practices and failure to follow facility policies and procedures in order to promptly identify new skin breakdown requiring treatment, placed residents at risk of death or serious physical harm."

CMS thus found that the Facility was substantially noncompliant with 29 regulatory requirements, three of which were of immediate jeopardy severity. CMS notified the Facility of a $4,050 daily CMP, an amount within the range authorized for immediate jeopardy violations, until the jeopardy was abated. The OIG conducted a revisit of the Facility on June 26, 2001 and determined that the immediate jeopardy had been removed as of June 20, but also that BNH was still

not in compliance. The OIG conducted a second revisit on September 11, 2001, and now determined that the Facility had been in substantial compliance with all regulations as of June 20, 2001. Therefore, CMS assessed a $24,300 CMP. BNH appealed, and a hearing was conducted before the ALJ in May 2002. On January 29, 2004, the ALJ affirmed in part CMS's determination. BNH appealed to the DAB, but the Board affirmed the decision on February 9, 2005. BNH subsequently filed a timely notice of appeal. The sole issue before us is whether substantial evidence supports the Department's finding that the undisputed facts constituted violations at the immediate jeopardy level with respect to pressure sore treatment and infection control.

II

A

Federal regulations impose significant requirements on skilled nursing facilities, such as BNH, that choose to participate in Medicare and Medicaid. "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25. "Substandard quality of care means one or more deficiencies related to participation requirements under . . . [42 C.F.R.] § 483.25, . . . which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm." 42 C.F.R. § 488.301.

The Department is authorized to impose a CMP on a facility that is out of compliance with 42 C.F.R. § 483.25. "The Secretary may impose a civil money penalty in an amount not to exceed $ 10,000 for each day of noncompliance." 42 U.S.C. § 1395i-3(h)(2)(B)(ii). "Penalties in the range of $ 3,050 - $ 10,000 per day are imposed for deficiencies constituting immediate jeopardy." 42 C.F.R. § 488.438(a)(1)(I).

"Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The Department's response to comments regarding providers' rights to challenge determinations of scope and severity provides a useful gloss:

> We believe that a provider's burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility's obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred, but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.

Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994) (to be codified at 42 C.F.R. Pts. 401, 431, 435, 440, 441, 442, 447, 483, 488, 489, & 498). Thus, the regulations affirmed that determinations of scope and severity could not be predicted with mathematical precision.

In the manual drafted to assist state surveyors and to promote uniformity in enforcement, CMS generally describes immediate jeopardy as "a crisis situation in which the health and safety of individual(s) are at risk." Ctrs. for Medicare and Medicaid Servs., U.S. Dep't of Health & Human Servs., CMS Pub. 100-07, Appendix Q – Guidelines for Determining Immediate Jeopardy, CMS Program Manuals (CCH) P Appendix Q (Rev. 1, May 21, 2004) at Q-2. In discussing the standard for immediate jeopardy, CMS notes that "only **ONE INDIVIDUAL** needs to be at risk" and that "**Serious harm, injury, impairment, or death** does **NOT** have to occur before considering Immediate Jeopardy. The high potential for these outcomes to occur in the very near future also constitutes Immediate Jeopardy." *Id*. at Q-3 (emphasis in original). However, the manual stressed that "Immediate Jeopardy procedures must not be used to enforce compliance quickly on more routine deficiencies." *Id*. at Q-4. Among the "triggers" that should initiate an investigation as to whether immediate jeopardy violations have occurred are "Pervasive improper handling of body fluids or substances from an individual with an infectious disease," a "pattern of ineffective infection control precautions," the "Failure to adequately monitor and intervene for serious medical/surgical conditions," and the "Failure to carry out doctor's orders." *Id.* at Q-5 – Q-8.

The Department has established through its regulations a minimum standard of care with which facilities must comply in order to continue their participation in the program and to avoid the imposition of civil money penalties. For the purposes of this appeal, two regulations are applicable: pressure sore treatment and infection control. The standard of care for pressure sores requires facilities to

> ensure that (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and, (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c). "This preventive focus of the regulation directs facilities to provide a certain standard of care to prevent the risk of pressure sores for its residents, even if no pressure sores actually develop." *Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168, 175 (6th Cir. 2004). As the regulations state with respect to infection control:

> [T]he facility must establish an infection control program under which it: (1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.

42 C.F.R. § 483.65(a)(1)-(3).

CMS's evidence that BNH's violations warranted the imposition of immediate jeopardy CMPs was largely restricted to the surveyors' observations and their conclusions. With respect to pressure sore treatment and prevention, OIG's surveyors concluded that the development of the pressure sore on Resident 2's left heel represented a "failure to provide pressure sore treatment in accordance with accepted infection control practices and [a] failure to follow facility policies and

procedures in order to promptly identify new skin breakdown requiring treatment, plac[ing] residents at risk of death or serious physical harm." With respect to infection control, the surveyors noted that the Facility and its staff (1) failed to employ appropriate infection techniques when providing pressure sore treatment, (2) failed to apply medications appropriately to the sores, (3) failed to remove feces from the residents' skin before providing treatment in two cases, (4) failed to ensure that an effective infection control program had been implemented to prevent the spread of infection, (5) failed to ensure that all resident infections were tracked and analyzed through its infection control program, and (6) failed to ensure that its staff used appropriate techniques to prevent the spread of infection. The surveyors concluded that "[t]his placed residents of the facility at risk for death or serious physical harm."

At the ALJ hearing, several surveyors testified in support of their determination of the severity of BNH's noncompliance. Robert Durham, a pharmacist who headed the survey team, stated that the reason for determining that the noncompliance warranted the immediate jeopardy tag was the Facility's "process of improper wound care treatment in which our Registered Nurses . . . [who] were assigned to specific observations did observe wound treatments in which fecal material was pulled into or left in the wound or covered over the wound." This caused the team to launch an investigation because "[t]he federal process mandates that once immediate jeopardy is – or even a concern that there may be immediate jeopardy, that we further investigate that in lieu of other things and go to the completion of that determination." That investigation included reviewing the surveyors' findings with their regional program managers and "some State guidance."

With respect to the fecal contamination of the wounds, Leslie Wyatt, a registered nurse, testified that

> [a]ny bacteria can cause a wound infection. With [where] this wound was and everything, it would be . . . the more common. Wounds are kind of a breeding ground for infection anyway, with the open area, the moisture, the warmth. And then with a dressing change, you're going to make all of this worse because you're going to put the covering over it, which is going to keep it moist. It's going to keep it warmer and keep it contained in the site, keep the feces contained in the wound.

Wyatt also testified with respect to Resident 4 who had a catheter and who had a bowel movement during the dressing change:

> when you do proper catheter care you wipe [the feces] from the front to the back to avoid getting feces around the catheter into the urethra, [which would] put the resident at risk for a urinary tract infection . . . . [but] they did not do any proper catheter care while I was in the room.

The result of this unsanitary behavior was to "put[] them at higher risk – what I observed in the dressing change placed her at risk for both a wound infection and a urinary tract infection."

Phillis Monhollen, an OIG surveyor who is also a registered nurse, observed Resident 13's treatment. She complained that the nurse had used unsterilized scissors that she had taken from her own pocket to cut soiled and clean bandages, and that she had contaminated a tube of ointment and yet continued to use that same contaminated tube to treat the patient's pressure sores. Monhollen also testified that, after the resident "had stooled," she witnessed the nurse take "her hands and . . . pushed that stool into . . . , up and under the resident with the bed sheets. They didn't clean the resident before beginning the pressure sore treatment." Monhollen worried that the feces might have contaminated the pressure sore. She was also concerned that the nurse had repositioned the

resident's body using gloves that had been soiled with the resident's feces. These observations led her to believe, in her professional opinion, that this had represented an immediate jeopardy situation because "they did not provide pressure sore treatment to this [resident] using the standard precautions that we use, and with hand washing and infection control practices, to prevent infection."

BNH sought to counter this evidence in a way that is substantially identical to its present position on appeal. BNH first asserted that the severity of any harm stemming from the observed acts was entirely theoretical as the government failed to introduce scientific evidence identifying the precise amount of increased risk to the residents arising from the observed noncompliant acts. To support this argument, BNH cited several articles from peer-reviewed medical journals suggesting that it is difficult to ascertain with precision the effectiveness of infection control techniques, and BNH then suggested that the step between colonization of a wound by bacteria and actual infection is a long and uncertain one. BNH also argued that any resulting infection would have been discovered and treated by its physicians, ensuring that the real risk of infection was minimal. BNH then posited that the concept of immediate jeopardy requires that the forecasted harm occur within hours or a day at most of the causal event. As any infection arising from the observed acts would likely require more than a few days to develop, BNH suggested that the increased risk of such infections cannot, *ipso facto*, warrant a finding of immediate jeopardy severity. Finally, BNH argued that the government was simply incorrect in stating that its infection control program was ineffective because its conclusions were based on an incomplete reading of the facility's program,

and, moreover, the facility argued that the program was successful because it had not experienced any outbreak of infection in the past.

The ALJ ruled that CMS's determination in this matter was not clearly erroneous. With respect to pressure sore treatment, the ALJ concluded:

> Even a credible showing that the Facility provided consistent overall pressure sore care does not demonstrate that CMS's assessment of the risk to the Residents was clear error. Asserting that harm to residents was theoretical, and therefore not likely, immediate or serious, does not carry Petitioner's burden to show that CMS's perspective, . . . was clear error. Petitioner's assertion that harm was not likely, immediate, or serious does not establish the fact and, therefore, does not establish that CMS erred. And, . . . a history of generally competent care does not excuse or outweigh specific instances of deficient care. The instances of deficient care are what CMS determined presented the jeopardy – the suggestion that potential harm presented by deficient care would be undone by consistent care provided after the fact is insufficient to demonstrate it was clearly erroneous to determine that Residents were likely to suffer serious harm from infection and or worsening pressure sores or development of new pressure sores.[2]

[2]BNH asserts that the ALJ incorrectly shifted the burden of persuasion to the Facility after the ALJ determined that CMS had made a *prima facie* showing to justify the CMP. CMS has the so-called *Hillman* rule, which has not yet been affirmed by any circuit. *Fairfax Nursing Home, Inc. v. U.S. Dep't of Health & Human Servs.*, 300 F.3d 835, 840 n. 4 (7th Cir. 2002), *cert. denied*, 537 U.S. 1111 (2003). In *Hillman Rehab. Ctr. v. United States*, DAB No. 1611, 1997 HHSDAB LEXIS 547 (Feb. 28, 1997), *aff'd Hillman Rehab. Ctr. v. U.S. Dep't of Health & Human Servs.*, No. 98-3789(GEB), slip op. at 25 (D.N.J. May 13, 1999), the Board held that, in termination hearings, the sanctioned facility bears the burden of rebutting the Department's *prima facie* showing. *Id.* at 1. This rule was extended to civil money penalties in *Cross Creek Health Ctr. v. Health Care Fin. Admin.*, DAB No. 1665, 1998 HHSDAB LEXIS 65 (July 14, 1998). This so-called *Hillman* rule operates when the *prima facie* evidence stands in equipoise, *Ivy Woods Healthcare & Rehab. Ctr. v. Thompson*, No. 04-4164, 156 F. App'x 775, 778-79 (6th Cir. Oct. 19, 2005). As in *Fairfax*, the weight of the evidence introduced by CMS in the instant case makes it unnecessary to determine the *Hillman* rule's correctness.

Moreover, the ALJ affirmed CMS's determination of immediate jeopardy with respect to infection control:

> Petitioner's supposition that no harm would likely befall residents within hours is an alternative, albeit arguably plausible, scenario for what would result from the deficient infection control program, but it is not effective to show the clear error of CMS's judgment that the deficient infection control program would likely cause more, and more prolific infections, i.e., serious harm to residents. In fact, implicit in Petitioner's argument is the apparent harm that is the concern. If the recognition of trends in infection is valuable, presumably it is so because it protects residents from the spread and worsening of infection. What precise harm to residents is presented by a delay in recognizing such trends is hard to say, but it is speculative of Petitioner to assert that the delay presents so minimal a risk to residents that it shows that CMS must have been clearly erroneous to determine the delay would likely lead to serious harm. If recognition of trends [in] infection is important to infection control, it is reasonable to surmise that the delay in the recognition, or the failure to apprehend a trend would likely cause serious harm to residents.

The DAB affirmed the ALJ's decision, concluding "that the ALJ properly upheld that determination since BNH failed to establish that the undisputed facts regarding the nurse's treatment of the pressure sores on Resident 4's coccyx cannot reasonably be viewed as supporting an immediate jeopardy determination." The DAB rejected BNH's argument that any resulting infections would not be severe because the infections would be treated, noting instead that the government introduced evidence that even local infections can cause wounds to be "slow to heal" and involve "more pain," qualifying as severe harm. The Board also rejected BNH's argument that the Facility would have spotted and treated any developing infections because "it is simply speculative . . . to assume that Resident 4's contaminated dressing would have been changed as a result of routine care," especially in light of the fact that dressings are not changed at the Facility unless they are found to be soiled during a visual examination.

The Board also rejected BNH's argument that any potential injury to the residents would not have occurred immediately, concluding instead that "BNH offered no evidence that supports its position that any serious harm would be remote in time from the care in question." In particular, the DAB noted that the evidence relied upon by BNH – a set of guidelines for treatment of pressure ulcers – was inapt because those guidelines stated that topical antibiotics would be adequate when patients have been given "optimal care," yet the Board noted that "clearly BNH did not provide 'optimal care' for Resident 4's pressure sore at the outset." Moreover, even if "it were not appropriate to begin the course of treatment with antibiotics until several weeks after the contamination occurred, that does not mean that the resident would not experience serious harm in the interim in the form of 'more pain' as a result of the infected pressure sore."

The Board affirmed the ALJ's decision with respect to the Department's determination of immediate jeopardy. The Facility had argued that "notwithstanding the omission from its tracking log of the items of information noted by the ALJ, BNH had 'multiple systems' of infection control and did not experience any systemic problems with the spread of infection." The DAB rejected this line of reasoning, stating that the systems described by the Facility "did not provide a means for tracking infections other than those being treated with antibiotics," and concluded that the "fact that BNH was not experiencing any problem with the spread of infections at the time of the survey would not preclude a finding of immediate jeopardy since the definition of immediate jeopardy does not require actual harm, only a likelihood of serious harm." In addition, the DAB decided that "it is reasonable to conclude that, in the absence of a system that tracked infections other than those being

tracked by antibiotics, such infections could spread unchecked, causing serious harm." As a result, "[t]here was a likelihood that serious harm was imminent since it is common knowledge that some types of infections can spread in a matter of days, if not sooner."

B

We have jurisdiction to review the Department's imposition of CMPs on facilities participating in the Medicare or Medicaid programs. "Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides." 42 U.S.C. § 1320a-7a(e). "Upon such filing, the court [of appeals] shall have jurisdiction of the proceeding and of the question determined therein." *Ibid.* However, the law requires us to apply a highly deferential standard of review. *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). "The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive." 42 U.S.C. § 1320a-7a(e). *See MeadowWood Nursing Home v. U.S. Dep't of Health & Human Servs.*, 364 F.3d 786, 788 (6th Cir. 2004). "In reviewing the Secretary [of HHS]'s interpretation of regulations, courts may overturn the Secretary's decision only if it is 'arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law.'" *St. Francis Health Care Ctr. v. Shalala*, 205 F.3d 937, 943 (6th Cir. 2000) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). "Further, courts are to 'give substantial deference to an agency's interpretation of its own regulations.'" *St. Francis*, 205 F.3d at 943 (quoting *Thomas Jefferson Univ.*, 512 U.S. at 512). "In sum, if 'it is a reasonable regulatory

interpretation we must defer to it.'" *St. Francis*, 205 F.3d at 944 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 94-95 (1995)) (internal alterations omitted).

BNH does not here dispute that it was in substantial noncompliance with the aforementioned regulations, nor does it challenge the general reasonableness of the CMPs that were levied.[3] Rather, BNH quarrels with the Department's determination that its noncompliance was so severe that it warranted the imposition of immediate jeopardy CMPs. In light of our highly deferential standard of review, the relevant question for this court is not whether the Department *could* have reached a different conclusion with respect to the severity of the Facility's noncompliance, but whether the Department's conclusion is supported by substantial evidence. That is to say, we must ascertain whether the Department's conclusion was *one* of a number of conclusions that could have been reached logically and reasonably based on the evidence before us; we do not need to determine whether the Department's conclusion is the *only* one that could have been so reached.

A provider can rest its case on the Department's ability or inability to introduce sufficient evidence to withstand our review for substantial evidence, or, alternatively, a provider can try to rebut enough of the Department's evidence so that, if successful, the surviving evidence is insufficient to meet our deferential threshold. BNH chose the latter approach.

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[3]The ALJ restricted his decision to 5 of the 17 tags that were disputed before him, declaring "It is not necessary for me to decide whether Petitioner was compliant with the requirements under the 12 remaining F-tags because the amount of the civil money penalty would not be affected if I concluded Petitioner substantially complied with those requirements. I therefore exercise my discretion to limit this decision to the aforementioned five F-tags." The ALJ focused on the two immediate jeopardy findings as well as three minor F-tags "because these determinations are supported by the same facts underlying F-314 and F-441."

It would have been a sounder litigation tactic for the Department to have introduced more expert testimony or evidence to reinforce its determination that the undisputed mistreatments observed at the Facility threatened serious harm to the residents. Nevertheless, we find that the expert observations and professional opinion testimony of the surveyors provide substantial evidence that the Facility's noncompliance warranted application of the immediate jeopardy level of severity. The Department thus met its obligation to introduce substantial evidence to support its determination that the Facility was substantially noncompliant with the applicable laws, and, further, that its noncompliance was such that the Department was authorized to levy immediate jeopardy civil money penalties.

BNH argues on appeal that CMS's determination as to the level of severity of the noncompliance is incorrect because (a) it is unlikely that any infections would result from the contamination of the wounds, and, even if an infection occurred, such infections would be of minimal severity because they would be detected early and treated effectively, (b) any serious infections that arise despite the Facility's treatment would take more time to develop than is warranted under the immediate jeopardy standard, (c) there are no established standards for infection control programs, so the government is essentially holding the Facility culpable for failing to follow an unknown standard, and the government conducted an incomplete reading of the facility's program, and (d) there have not been any outbreaks of infection at the Facility in the past, belying CMS's claim that the Facility's failure to abide by accepted infection control techniques risks

serious harm to the residents. Importantly, however, BNH does not refute the determination that one resident developed an avoidable pressure sore.

BNH attempted to rebut the Department's evidence. The evidence that the Facility introduced is not insubstantial. However, it is also not dispositive, nor is it sufficiently persuasive that it fatally undermines the substantial evidence upon which the Department relied in concluding that the Facility's substantial noncompliance constituted immediate jeopardy for its residents.

The Facility contended that infection control programs, including the tracking of infections through careful administrative procedures, are of questionable importance because such programs are supported by only limited clinical evidence, and BNH further asserted that there is no evidence that the failure to have such a program would likely result in serious harm. But such programs are mandated by law, a fact that trumps any clinical evidence to the contrary. Moreover, this line of argument has already been rejected by the ALJ ("If recognition of trends [in] infection is important to infection control, it is reasonable to surmise that the delay in the recognition, or the failure to apprehend a trend would likely cause serious harm to residents") and the Board ("it is reasonable to conclude that, in the absence of a system that tracked infections other than those being tracked by antibiotics, such infections could spread unchecked, causing serious harm"). We see no reason to disagree, as it was reasonable for the government to conclude that the absence of adequate infection tracking procedures would likely result in serious harm to residents should there occur an outbreak. Modern medical procedures may be able to heal many infections, but can only do so after the infections are discovered, and in the meantime the safety of residents would be at risk of serious

harm. Prevention is equally important as treatment, and the absence of adequate tracking means that the resident would have already suffered pain and would have been placed at risk of more serious complications even if the facility could treat avoidable infections with pharmaceutical products.

BNH's argument with respect to the unlikelihood that any infection would result in serious harm because even those infections that develop would be caught and treated by BNH's physicians is purely speculative; in fact, it is nearly bizarre for a facility that unquestionably had been observed mistreating its residents to argue that the superb quality of its future treatment would prevent any harm from developing as a result. More damning still is the fact that BNH does not refute the determination that one of its residents developed an avoidable pressure sore at the Facility, demonstrating that the Facility's mistreatment caused actual, not just potential, harm to its residents. Furthermore, BNH's argument suggests that the government must prove with precision the exact increase of risk to the patients as a result of BNH's mistreatment, which would entail an immensely higher standard of proof than the law presently requires.

Moreover, BNH's argument that any serious harm must occur within a day of the treatment in order to warrant immediate jeopardy treatment is invalid. Neither the regulations nor any court has heretofore held that a strict numeric standard applies to the determination of immediate jeopardy. *See Hermina Traeye Mem'l Nursing Home v. Ctrs. for Medicare and Medicare Servs.*, DAB No. 1810 at 7 (2002), *aff'd sub nom. Sea Island Comprehensive Health Care Corp. d/b/a Hermina Traeye Mem'l Nursing Home v. U.S. Dep't of Health & Human Servs.*, No. 02-2076, 79 F. App'x 563 (4th Cir. Oct. 29, 2002) (immediate jeopardy does not depend on a "crisis" situation or "a

presently existing threat" for the imposition of CMPs). The concept of "harm" includes pain, which could occur quite quickly in case of a serious infection. If death or serious harm could result if an infection arising from a facility's mistreatment of a resident is not treated properly and promptly, then the causal act of mistreatment warrants application of the immediate jeopardy level of severity.

Finally, with respect to BNH's claims that there are no established standards for infection control programs, that infection control programs are supported by only limited clinical evidence, that the government misread the facility's program, and that BNH's lack of infectious outbreaks in the past constitutes dispositive evidence that its program was effective, the agency's determination remains quite persuasive. Whatever the merits of the Facility's past practices, the fact that behavior was directly observed that violated BNH's own policies on infection control, as well as generally accepted medical techniques, simply overwhelms any circumstantial evidence of proper behavior in the past that BNH has mustered. Future injury caused by present mistreatment is simply not cured by claims of past virtue.

III

We **AFFIRM** the Department's determination that BNH's substantial noncompliance caused immediate jeopardy to its residents that warranted $24,300 in CMPs.